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10/535,617	02/06/2006	Franco Bartoli	GK-ZEI-3279/500343.20300	7497
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REED SMITH, LLP ATTN: PATENT RECORDS DEPARTMENT 599 LEXINGTON AVENUE, 29TH FLOOR NEW YORK, NY 10022-7650			EXAMINER HUNTER, RONALD A	
			ART UNIT	PAPER NUMBER
			3769	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/535,617

**Applicant(s)**

BARTOLI, FRANCO

**Examiner**

RONALD HUNTER

**Art Unit**

3769

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

The informal drawings are not of sufficient quality to permit examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Applicant is given a TWO MONTH time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

### ***Claim Objections***

***Claims 18-31:*** *it is unclear whether the sub-steps/structures are critical to the inventive concept or just provide additional additive information, hence, the numbering renders the claims ambiguous. Examiner requests a rewrite of claim language. Also, examiner has taken broadest interpretation of the claim language.*

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 18-31** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claims 18-24:** *it is unclear whether the claims refer to treating presbyopia or other visual defects. Examiner has taken broadest interpretation of the claim language.*

**Claim 23 & 30:** *it is unclear what applicant's definition of defect, as emmetropia is commonly defined as 20/20 vision.*

**Claim 23 & 30:** *it is unclear how to interpret Zernike coefficients, as they are dependent upon pupil diameters of the eye.*

**Claim 31:** *it is unclear why there is a need for a second control means for correcting higher order aberrations after inducing a 4th order aberration.*

**Claim 21(a4)** recites the limitation "so generated" in line 1. There is insufficient antecedent basis for this limitation in the claim.

**Claim 30(c1)** recites the limitation "maximum 6 mm inside diameter" and "maximum 9 mm outside diameter" in lines 1 & 2. There is insufficient antecedent basis for this limitation in the claim.

**Claims 18-34** are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

**Claim 18:** *the steps of acquiring and interpreting optical information of eye in order to diagnose and correct optical defect(s).*

**Claim 21:** *the step of interpreting optical information of eye in order to differentially diagnose and correct optical defect(s).*

**Claim 23:** *the steps of interpreting optical information of eye in order to differentially diagnose, determine surgical efficiency and correct optical defect(s).*

**Claim 24:** *the steps of acquiring and interpreting optical information of eye in order to diagnose and correct optical defect(s).*

**Claim 32:** *the steps of acquiring and interpreting optical information of eye and controlling an irradiation source in order to diagnose and correct optical defect(s).*

**Claim 28** is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: *Structure capable of interpreting optical information of eye in order to differentially diagnose, determine surgical efficiency and correct optical defect(s).*

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 18-22, 24-29, 31-34** are rejected under 35 U.S.C. 102(b) as being anticipated by **Williams et al. (US 6,394,999 B1)**.

**Regarding claim 18-20, 22, 24, 26, 27, 29, & 32-34**, William et al. disclose a method for laser ablation (*controlling a laser*) or reshaping of the eye (*specific photoablative treatment*) which considers higher order aberrations of the eye (*column 3, lines 41 & 42*) and by expanding mathematical equations for refraction correction to include higher order effects, coma (3rd order) and spherical (4th order) aberrations can be reduced (*column 3, lines 8-11*), a negative asphericity of the normal cornea contributes a negative aberration content. The negative aberration is compensated by a positive aberration contribution (*inducement*) from the gradient index nature of the lens (*column 3, lines 20-22*) and the excimer laser is used to remove or ablate tissue from the cornea in order to flatten its shape, *wherein a positive spherical inducement in the in the 4<sup>th</sup> order inherently associated to presbyopia treatment*.

**Regarding claim 21**, Williams et al. disclose wavefront sensing provides an overall refractive analysis of the entire eye optical system (*acquiring aberrometric map*),

e.g., taking into account the cornea, the lens, the vitreous and the retina (*column 4, lines 20-22*), in the treatment of myopia (*negative spherical aberration*), the excimer laser is used to remove or ablate tissue from the cornea in order to flatten its shape (*induce positive spherical aberration*) (*column 1, lines 24-26*). The examiner interprets the claims as written in a conditional format, therefore only one "if" condition for each claim needs to be met.

**Regarding claim 25**, recites "first control means for controlling laser" these terms are interpreted as invoking 35 U.S.C. 112, sixth paragraph as it includes functional language and does not include sufficient structure for achieving the specified function.

Williams et al. disclose a computer system **20** (*means for controlling laser*), a laser **22** for producing a laser beam capable of making refractive corrections, an optical system **24** for shaping and conditioning the laser beam, a DMD **26**, and an eye tracking system **28** (*Fig. 1; column 6, lines 12-15*).

**Regarding claim 28**, recites a "generating means" and "means for acquiring," these terms are interpreted as invoking 35 U.S.C. 112, sixth paragraph as it includes functional language and does not include sufficient structure for achieving the specified function.

Williams et al. disclose a computer system **20**, a laser **22** (*photoablative pattern generating means*) for producing a laser beam capable of making refractive corrections, an optical system **24** for shaping and conditioning the laser beam, a DMD **26**, and an eye tracking system **28** (*means for acquiring*) (*Fig. 1; column 6, lines 12-15*) and a

negative asphericity of the normal cornea contributes a negative aberration content. The negative aberration is compensated by a positive aberration contribution (*inducement*) from the gradient index nature of the lens (*column 3, lines 20-22*).

**Regarding claim 31**, recites "second means for controlling the excimer laser unit" these terms are interpreted as invoking 35 U.S.C. 112, sixth paragraph as it includes functional language and does not include sufficient structure for achieving the specified function.

William et al. disclose a method for laser ablation (*controlling a laser*) or reshaping of the eye (*specific photoablative treatment*) which considers higher order aberrations of the eye (*column 3, lines 41 & 42*). Examiner interprets *controlling the laser to operate in respect to a higher order parameter other than the 4<sup>th</sup> as a second means for controlling*.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 23 & 30** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Williams et al. (US 6,394,999 B1)** as applied to claims 18 & 25 in view of **[C. E.**



***Martinez et al., "Changes in corneal aberration structure after photorefractive keratectomy."***

Regarding claims 23 & 30, William et al. are discussed above but, fail to teach ablation with a customized ablative pattern to obtain even greater spherical aberration with a coefficient of Zernike's polynomial  $Z_{-4}^0$ .

However, Martinez et al. teaches that spherical aberration is highly correlated with best spherical-correlated visual acuity in normal eyes and results show for 4<sup>th</sup> order aberration ( $S_4$ ) postoperative surgery, the Zernike coefficient for 60 patients with 7-mm pupil diameters equals 0.9999 (Table 5; par. 9, lines 3 & 4) and fourth-order Zernike coefficients  $Z_{11}$  through  $Z_{15}$  are indicators of spherical-like aberration. When values were calculated for a 3-mm pupil (Table 3),  $Z_{11}$ ,  $Z_{12}$ , and  $Z_{14}$  had changed by 1 month after surgery and never returned to preoperative values. In the 7-mm pupil calculations (Table 4), coefficients  $Z_{11}$  and  $Z_{14}$  had changed by 1 month after surgery ( $P < .001$ ) (par. 27 [Zernike Coefficients]), wherein patient's eyes are observed in location with dim lighting, causing the pupil to dilate.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the positive spherical aberration of William et al. by modifying the Zernike coefficient to equal 0.999 as taught by Martinez, therefore reducing the effects of presbyopia in the 4<sup>th</sup> order. The examiner interprets the claims as written in a conditional format, therefore only one "if" condition for each claim needs to be met.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitations of the applicant's claimed and disclosed invention: **Williams et al. (US 5,777,719 A)**, **Bille et al. (US 6,050,687 A)**, **Frey (US 6,271,914 B1)**, **Guirao (US 6,511,180 B2)**, **Thomas (6,561,648 B2)**, **Norrby et al. (US 6609793 B2)**, & **MacRae et al. (US 2006/0235369 A1)**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUNTER whose telephone number is (571)270-7133. The examiner can normally be reached on Monday - Friday, 9:00am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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